REMARKS/ARGUMENTS

Claims 172-178 and 186 are pending in the above-referenced application.

This is a response to the Final Office Action dated December 5, 2007 wherein the Examiner rejected: (1) claims 172-178 and 186 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent or Application Nos. 2001/0044482 (Hu et al.), 4,123,408 (Gordon), or 4,462,665 (Shah), each taken in view of U.S. Patent Nos. 5,338,408 (Dziabo) and 3,954,644 (Krezanoski); and (2) claims 172-178 and 186 under 35 U.S. C. 103(a) as being unpatentable over U.S. Patent Nos. 6,008,170 (Tanaka et al.) or 6,440,366 (Salpekar et al.), each taken in view of Dziabo (5,338,408) and Krezanoski (3,954,644).

In view remarks that follow, reconsideration of the rejections and a notice of allowance are respectfully requested.

§103(a) Rejection of Claims 172-178 and 186 by Hu, Gordon or Shah each taken in view of Diazebo and Krezanoski

In rejecting claims 172-178 and 186, the Examiner contends that any one of Hu, Gordon or Shah discloses the claimed contact lens and Diazebo and Krezanoski disclose contact lens storing and cleaning solutions using the polymers claimed in the instant application. The Examiner concludes that it would have been obvious for a skilled artisan to combine any one of the primary references with any one of the secondary references to come up with the instant invention and therefore to render the claims obvious.

Preliminarily, Applicant reminds the Examiner that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP 706.02(j).

Applicant submits that the present claims are patentable over the cited references, taken alone or in any combination, because the references do not teach or suggest all of the elements recited in the present claims, and a person of ordinary skill in the art would not be motivated to combine the deficient teachings of the references, let alone do so and obtain the presently claimed invention. Thus, Applicant submits that the rejection under 35 U.S.C. § 103(a) is improper and cannot be properly maintained.

Independent claim 172 recites a package system comprising: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol. (emphasis added)

Thus, among other features, claim 172 specifically recites that the molded contact lens AND the packaging liquid medium comprise the SAME water soluble polymer component. Still furthermore, even if a prior art reference or a combination of references teaches a lens and a packaging liquid having the same water soluble polymer component, the water soluble component must be a polyalkylene glycol. The cited references simply do not teach the presence of a polyalkylene glycol in the contact lens and in the sterile packaging solution, as recited in the present claims.

The Examiner relied on Hu, Gordon or Shah to disclose the claimed contact lens.

The 2001/0044482 Hu application discloses hydrogel contact lenses comprising an interpenetrating polymer network (IPN) composition. The IPN comprises at least one polymer which is formed through the polymerization of monomers, and at least one IPN agent. Monomers that could be used in the formation of the polymer include a long list of various compounds ([0019] and [0029]). IPN agents include but are not limited to polyvinylpyrrolidone (PVP) or poly-2-ethyl-2-oxazoline (PEOX) or poly(4-vinylpyridine N-oxide) (PVNO) or their mixtures ([0019]). Applicant respectfully submits that although the Hu application may broadly

encompass hydrogel contact lenses that include an IPN, the Hu application does not specifically disclose or suggest a cast molded contact lens that includes the water soluble polymer component, polyalkylene glycol.

The '408 Gordon patent discloses hydrogel contact lenses comprising various polymers which can be worn in the eye with a minimum of discomfort or irritation (Col. 2, lines 42-45 and col. 4, line 45 to col. 5, line 10). Gordon specifically teaches how to make lathed contact lenses (col. 9, lines 19-25). As known to persons of ordinary skill in the art, lathed contact lenses are physically different and distinct from cast molded contact lenses, for example, differences in contact lens surfaces exist between lathed contact lenses and cast molded contact lenses. Thus, Gordon clearly does not disclose the features of the claimed contact lens, which is a cast molded contact lens body that comprises a polyalkylene glycol.

The '665 Shah patent discloses polymer blends capable of forming hydrogels which are compatible with vinyl lactam polymers to form laminates. As described, Shah specifically teaches how to make laminated contact lenses (col. 7, line 55 to col. 8, line 62). As would be apparent to one of ordinary skill in the art, laminated contact lenses are physically different and distinct from cast molded contact lenses. Furthermore, Applicant respectfully submits that nowhere in the Shah patent is disclosed a cast molded contact lens includes a water soluble polymer component that is polyalkylene glycol.

The Examiner relied on Diazebo and Krezanoski to disclose packaging solutions.

The '480 Dziabo patent discloses compositions and methods for cleaning contact lenses, comprising enzymes and a disinfectant destroying component to destroy the disinfectant which interferes with the activity of the enzyme. The composition contains delayed release components which serve to delay the release of the enzyme and disinfectant destroying component, containing polymers listed in col. 5, lines 65 to col. 6, line 14.

The '644 Krezanoski patent discloses cleaning solutions for silicone and hydrogel contact lenses, containing block copolymer of polyoxyethylene - polyoxypropylene, microbial growth inhibitor, and salt solution.

Applicant submits that cleaning solutions are different and distinct from packaging solutions. Indeed, packaging solutions and cleaning solutions are not viewed as interchangeable

by a person of ordinary skill in the art. Packaging solutions are regulated by the FDA as part of the initial contact lens package and therefore must remain sterile until use. The disclosure of US 6,440,366 clearly highlights these differences: "[Non-ionic surfactants] are well-known wetting and lubricating agents for contact lenses and have been used in lens wetting drops and in lens-care solutions for treating lenses after use" (Col. 1, lines 42-47) and "[f]urthermore, the difficulties of adding a surfactant to a packaging solution, including the possibility of lowering shelf-life and/or adverse reactions during heat sterilization, have further limited the use of surfactants a packaging solution" (Col. 2, lines 17-21).

The difference between packaging and cleaning solutions is reflected by the stringent FDA regulations on the former, as summarized by the '366 patent: "The [packaging] solution must be "ophthalmically safe" for use with a contact lens, meaning that a contact lens treated with the solution is generally suitable and safe for direct placement on the eye without rinsing" (Col. 4, lines 52-55) and that stringent requirement is further defined as "An ophthalmically safe solution has a tonicity and pH that is compatible with the eye and comprises materials, and amounts thereof, that are non-cytotoxic according to ISO standards and U.S. FDA (Food and Drug Administration) regulations. The solution should be sterile in the absence of microbial contaminants in the product prior to release must be statistically demonstrated to the degree necessary for such products" (Col. 4, lines 58-65). Thus, Applicant respectfully submits that nowhere in Diazebo and Krezanoski is disclosed a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body, and the sterile packaging liquid medium comprises a polyalkylene glycol, as recited by claim 172. The Examiner's bare assertion that a cleaning solution may be substituted for a lens packaging solution is simply incorrect, has no support in the art, conflicts with accepted practices in the art, is opposed by those skilled in the art, and violates the agency that is established to regulate packaging solutions for contact lenses, i.e., of the type claimed.

In view of the foregoing, Applicant respectfully submits that the deficient teachings of the cited references, even if combinable, fail to teach or suggest all the elements of claim 172 and therefore fail to render claim 172 obvious under 35 U.S.C. § 103, as required by MPEP 706.02(j). The references also fail as a combination as contact lens cleaning solutions cannot be

substituted for contact lens packaging solutions. Indeed, nowhere in the cited references, either individually or any permissible combination, is a package system disclosed that comprises: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol, as recited by claim 172. Thus, rescission of the §103(a) rejection of claim 172 is respectfully requested. Since claims 173-178 and 186 depend from claim 172, they too are allowable for at least the same reasons and allowance is respectfully solicited.

In the final Office Action, the Examiner states that argument previously presented by Applicant "ignores the teachings of the references" as "the cited references taken alone or in any combination [teach] contact lens package systems that include the recited contact lens and the sterile packaging liquid medium, wherein both the contact lens and the sterile packaging liquid medium comprise a polyalkylene glycol" (page 5, last paragraph). Applicant's review of the cited references however, did not reveal the teachings or disclosures relied on by the Examiner. Should the Examiner insist that the cited references disclose or suggest all the limitations and elements of the claimed package system, Applicant respectfully requests that the Examiner provides specific references (by page, column, line number, or paragraph number) to such disclosure in compliance with MPEP § 2260 and 37 CFR §104(c)[1], which require a clear and complete Office Action. In addition, Applicant respectfully requests that such an Office Action, if necessary, be made non-final since the present Final Office Action is defective in this regard.

[1] (c) (2) In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified. (emphasis added).

§103(a) Rejection of Claims 172-178 and 186 by Tanaka, or Salpekar each taken in view of Diazebo and Krezanoski

In rejecting claims 172-178 and 186, the Examiner contends that Tanaka and Salpekar disclose the claimed contact lens and Diazebo and Krezanoski disclose contact lens storing and cleaning solutions using the polymers claimed in the instant application. The Examiner concludes that it would have been obvious to a skilled artisan to combine the primary references with the secondary references to render the claims obvious.

The '170 Tanaka patent discloses cleaning solutions containing a protease in an amount effective for removing protein adhering or clinging to contact lenses, and gum arabic as a hydrophilicity rendering component, wherein divalent metal ions in the gum arabic are removed or inactivated (Abstract).

The Examiner cited, among others, the paragraph bridging column 3 to column 4 of Tanaka as disclosing "the contemplated contact lens employed in the instant claims". However, that paragraph primarily discloses a cleaning solution containing an additional thickener:

"In a further preferred form of the contact lens cleaning solution of the present invention, the cleaning solution further contains as an additional component a thickener such that an aqueous solution which contains only said thickener at the same concentration as a concentration of said thickener in said cleaning solution gives surface tension of not lower than 50 dyn/cm at ordinary temperature. The thickener is advantageously selected from the group consisting of: polyvinyl pyrrolidone, copolymer of methoxyethylene and maleic anhydride, xanthan gum, and hydroxyethyl cellulose." (Col. 3, line 62 to Col. 4, line 5).

Other citations referred to by the Examiner in the '170 Tanaka patent (i.e., Abstract, column 6 (lines 45-61), Examples and claims) also disclose primarily a cleaning solution. If a given contact lens is referred to, it is merely to describe the effect of such cleaning solution. Nowhere in the '170 Tanaka is disclosed a contact lens comprising a water soluble polymer component that is a polyalkylene glycol, as recited by the present claims.

The '366 Salpekar patent discloses packaging solutions using non-ionic surfactants containing polyoxyalkylene copolymers.

Similarly, the Examiner cited several disclosures in Salpekar as showing the "contemplated contact lens employed in the instant claims", such as the Abstract, column 3 (line 53) to column 7 (line 57), the Examples and the claims. The Abstract of Salpekar clearly states: "The present invention is directed to new and improved solutions for packaging contact lenses and to methods for treating contact lenses with such solutions to improve the comfort of the lenses during wear". If hydrogel contact lenses are referred to, it is to disclose which lens would benefit from such packaging solutions and also the effect of the claimed packaging solutions on the lenses. Thus, contact lenses that are made from methacrylic acid (MAA), or hydroethyl methacrylate (HEMA) or N-vinylpyrrolidone (NVP) are disclosed as lenses that could be used with the claimed packaging solution (col. 6, lines 55-62). However, nowhere in the '366 Salpekar patent is disclosed a contact lens comprising a water soluble polymer component that is a polyalkylene glycol, as recited by claim 172.

Nowhere in either the '170 Tanaka or the '366 Salpekar is disclosed the claimed molded contact lens of the claimed package system.

The Examiner relied on Diazebo and Krezanoski to disclose packaging solutions.

As set forth above, Diazebo and Krezanoski teach cleaning solutions, which by FDA regulations, have clearly very different requirements from packaging solutions.

In view of the foregoing, Applicant respectfully submits that the deficient teachings of the cited references are not combinable, as three of them (Tanaka, Diazebo and Krezanoski) disclose cleaning solutions (not contact lens packaging solutions) and the last one (Salpekar) teaches packaging solutions, which are not interchangeable with contact lens cleaning solutions, and thus the references fail to render claim 172 obvious under 35 U.S.C. § 103, as required by MPEP 706.02(j). Indeed, nowhere in the cited references, either individually, or even if assumed combinable, is disclosed a package system comprising: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded

contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol, as recited by claim 172. Thus, rescission of the §103(a) rejection of claim 172 is respectfully requested. Since claims 173-178 and 186 depend from claim 172, they too are allowable for at least the same reasons and allowance is respectfully solicited.

In the final Office Action, the Examiner alleges that argument previously presented by Applicant "ignores the teachings of the references" as "the cited references taken alone or in any combination [teach] contact lens package systems that include the recited contact lens and the sterile packaging liquid medium, wherein both the contact lens and the sterile packaging liquid medium comprise a polyalkylene glycol" (page 5, last paragraph). Applicant's review of the cited references however, did not reveal the teachings or disclosures relied on by the Examiner. Should the Examiner insist that the cited references disclose or suggest all the limitations and elements of the claimed package system, Applicant respectfully requests that the Examiner provides specific references (by page, column, line number, or paragraph number) to such disclosure in compliance with MPEP § 2260 and 37 CFR §104(c), which require a clear and complete Office Action. In addition, Applicant respectfully requests that such an Office Action, if necessary, be made non-final since the present Final Office Action is defective in this regard.

In view of the foregoing remarks, the application is thought to be in condition for allowance and early notice thereof is respectfully solicited.

Should the Examiner wish to speak with Applicant's attorney, he is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,
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